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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,579	10/16/2003	James C. Chen	59785-8	7765

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,579

Applicant(s)

CHEN, JAMES C.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-10-03; 5-24-05</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-24 are presented for examination.

Applicant's drawings filed October 16, 2003; preliminary amendment filed February 27, 2004; and the information disclosure statements filed November 10, 2003 and May 24, 2005 have been received and entered.

Applicant's election filed October 28, 2005 in response to the restriction requirement of August 30, 2005 has been received and entered. The applicants elected the invention described in claims 1-21 (Group I) without traverse.

Claims 22-24 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

In claim 1, line 8, after the word "or" the word "if" should be changed to --its-

-.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for photodynamic therapy for the reduction of adipose tissue with photosensitizing agent, mono-L-aspartyl chlorine e6 (NPe6), and its conjugated formed of Npe6 and monoclonal antibody to lipoprotein lipase, does not reasonably provide enablement for Npe6 prodrugs or the other photosensitizing agents or their prodrugs. The specification does not enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for photodynamic therapy for the reduction of adipose tissue or adipocytes in a mammalian subject comprising: administering to the subject a therapeutically effective amount of a photosensitizing

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agent or a photosensitizing agent delivery system or a prodrug, wherein said photosensitizing agent or said photosensitizing agent delivery system or prodrug selectively localizes in the adipose tissue or the adipocytes; irradiating at least a portion of the subject with light at a wavelength absorbed by said photosensitizing agent or its said prodrug, by a prodrug product thereof, wherein said light is provided by a light source; and wherein said irradiation is administered at a relatively low fluence rate that results in the activation of said photosensitizing agent or said prodrug product; and wherein said PDT drug is cleared from the skin and subcutaneous tissues of the subject prior to said irradiation.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the prodrugs of Npe6 and the other photosensitizing agents and their prodrugs disclosed in claims 8 and 9.

The breadth of the claims

The claims are very broad and inclusive to all photosensitizing agents or all photosensitizing agents delivery systems or prodrugs.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples, Examples 1 and 2, are limited to the administration of mono-L-aspartyl chlorine e6 (Npe6) for photodynamic therapy for the reduction of adipose tissue or adipocytes in a mammalian subject.

No examples showing other photosensitizing agents or photosensitizing delivery systems or prodrugs are used in the instant photodynamic therapy.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the prodrugs of Npe6 and the other photosensitizing agents of claims 8 and 9 are effective in the reduction of adipose tissue or adipocytes in mammalian subject. The level of experimentation needed to determine the prodrugs of Npe6 and the other photosensitizing agents of claims 8 and 9 to reduce adipose tissue or adipocytes is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-21 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolini et al. (5,954,710) in view of Chen et al. (5,445,608) and further in view of Bommer et al. (4,693,885) and Sato et al., "Lipoprotein Hydrolysis and Fat Accumulation in Chicken Adipose Tissue are Reduced by Chronic Administration of Lipoprotein Lipase Monoclonal Antibodies", Poultry Science, 78: 1286-1291, 1999.

Paolini et al. teach a device and methods for eliminating adipose layers by means of laser energy (See the abstract). Note the device is for the removal of subcutaneous adipose layers with a laser source, which emits at a wavelength with an optical fiber wherein the laser source of visible light is beamed subcutaneously (see column 3, lines 3-5).

The instant invention differs from the cited reference in that the cited reference does not teach addition of photosensitizing agents for photodynamic therapy. However, the secondary reference, Chen et al., teaches a method and apparatus for light-activated therapy. Chen et al. teach the method for photodynamic treatment at a site comprising the steps of: applying a photoactive agent, positioning a light source, and administering the light source to the treatment site. Note column 8, lines 57-59 states the absorption of light at the wavelengths, i.e. in the 700 to 1500 nm range, same as applicant's claim 11. The reference also teaches the light source is a light emitting diode. Clearly, one skilled in the art would have assumed the photodynamic therapy method of Chen et al. combined with the method of Paolini et al. would produce the applicant's instant invention is the absence of evidence to the contrary.

The tertiary reference, Bommer et al., was cited to show the mono-L-aspartyl chlorine e6 (Npe6) is a well-known photosensitizing agent for phototherapy. The Sato et al. reference teaches lipoprotein lipase monoclonal antibodies are known to reduce adipose tissue in chicken, but does teach the combination with a photosensitizing agent as disclosed in claims 14 and 15.

Claims 1-21 are not allowed.

The remaining references listed on the enclosed PTO-892 are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
January 12, 2006